JUL 1 2002

K013182

9 510K Summary

Submitted By:
Lisa Hopkins
Regulatory Affairs Coordinator
COOK INCORPORATED
925 South Curry Pike
P.O. Box 489
Bloomington, IN 47402
(812) 339-2235

Device:

Trade Name:	Triple Lumen Central Venous Catheter
Common/Usual Name:	Central Venous Catheter
Proposed Classification Name:	Intravascular Catheter 21 CFR Part 880.5200, FOZ

Intended Use:
The Triple Lumen Central Venous Catheter is intended for vascular access infusion and withdrawal of blood, blood products, and fluids, central venous blood pressure monitoring (CVP), plasma pheresis, acute hyperalimentation, continuous or intermittent drug infusion.

The device will be supplied sterile and is intended for one-time use.

Predicate Devices:

Cook Double Lumen Catheters	Marketed & Distributed by Cook Incorporated (Preamendment)
Arrow-Howes Large Bore Multi-lumen Central Venous Catheter	Marketed & Distributed by Arrow International K970864

Device Description
The Triple Lumen Central Venous consists of a three-lumen, silicone shaft and manifold hub. With three separate lumens, it is possible to infuse/withdraw several different medications simultaneously. The catheter will be available in 12.5 Fr. The catheter will be part of a set which contains a percutaneous entry needle, peel-away sheath, curved wire guide, introducer and Luer-slip syringe. This set will be supplied sterile, packaged in trays.

Substantial Equivalence:
The device will be manufactured according to specified process controls and a Quality Assurance Program, undergoing packaging and sterilization procedures similar to currently marketed devices. This device is similar with respect to intended use, and physical characteristics to predicate devices in terms of section 510(k) substantial equivalency.

Test Data:
Testing conducted on the Triple Lumen Central Venous Catheter includes:

- Tensile
- Flow
- Leak /Pressure
- Catheter Occlusion
- Biocompatibility

The results of these tests provide reasonable assurance that the device has been designed and tested to assure conformance to the requirements for its use as an intravascular catheter.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 1 2002

Ms. Lisa Hopkins
Cook, Incorporated
Regulatory Affairs Coordinator
P.O. Box 489
Bloomington, Indiana 47402-0489

Re: K013182/S2
Trade/Device Name: Triple Lumen Central Venous Catheter
Regulation Number: 21 CFR 880.5200
Regulation Name: Central Venous Catheter
Regulatory Class: II
Product Code: FOZ
Dated: April 24, 2002
Received: April 25, 2002

Dear Ms. Hopkins:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely,

Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K013182

Device Name: Triple Lumen Central Venous Catheter

Indications for Use:

A vascular access catheter used for, infusion and withdrawal of blood, blood products, and fluids, central venous blood pressure monitoring (CVP), acute hyperalimentation, continuous or intermittent drug infusion.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use_____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K013182/S2